

REMARKS

Applicant respectfully requests reconsideration. Claims 18-36, 51-59 and 64-69 were previously pending in this application. Claims 20, 21, 57 and 58 have been canceled. Claims 18, 19, 22-36, 51-55, 59, 64-66 and 69 have been amended. Support for the claims as amended are found throughout the specification and in the claims as filed.

No new matter has been added.

Rejections Under 35 U.S.C. § 112

Written Description

The Examiner rejected claims 18-22, 25-27, 31-33, 35 and 51-54 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicant has amended the claims and respectfully requests reconsideration.

The Examiner indicated that the claims are rejected because they are not supported by the disclosure as filed. More particularly, the asserted that the following material is not supported by the application as filed: “ ‘wherein said fragment consists essentially of’ a variable region or part of the variable region of a heavy polypeptide chain, said variable region being devoid of normal light chain interaction sites”. Office Action at page 3.

Applicant respectfully disagrees with the Examiner’s assertion because the alleged new matter is in fact described in the specification as filed. However, to advance prosecution of the claims, Applicant has amended the claims and has removed the particular terms found objectionable by the Examiner. Accordingly, in view of the claim amendments, this rejection is moot. Applicant reserves the right to pursue the subject matter removed from the claims by this amendment in a continuing application.

Accordingly, withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Indefiniteness

The Examiner rejected claims 18-22, 25-27, 31-33, 35 and 51-54 under 35 U.S.C. § 112, second paragraph, as indefinite. Applicant has amended the claims and respectfully requests reconsideration.

Specifically, the Examiner indicated that claims 18, 19, 51 and 52 are indefinite because of the recitation “consists essentially of”, because it is not clear “which are the unlisted ingredients that do not materially affect the basic and novel properties of the invention”. Office Action at page 3.

Applicant respectfully disagrees with the Examiner’s assertion because the basic and novel properties of the claimed variable region and polypeptides, etc., are clearly described in the specification as filed. However, to advance prosecution of the claims, Applicant has amended the claims and has removed the particular terms found objectionable by the Examiner. Accordingly, in view of the claim amendments, this rejection is moot. Applicant reserves the right to pursue the subject matter removed from the claims by this amendment in a continuing application.

Accordingly, withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Rejections Under 35 U.S.C. § 102

1. The Examiner maintained the rejection of claims 18-22, 25-27, 31-33, 35 and 51-53 under 35 U.S.C. § 102(b) as being anticipated by Ungar-Waron et al. (Isr. J. Vet. Med. 1987, Vol. 43(3), pages 198-203) as evidenced by Hamers-Casterman et al. (Nature 3 June 1993, Vol. 363, pages 446-448), Roux et al. (PNAS USA 1998, Vol. 95, pages 11804-11089), WO

94/25591, van der Linden et al. (Biochimica et Biophysica Acta 1999, 1431: 37-46), and EP 0739981 A1.

According to the Examiner, the teaching in Ungar-Waron et al. is of a 100 kD band that dissociates into a 40 kD band. The Examiner also asserts on pages 4 and 5 of the Office Action that the Ungar-Waron reference teaches a 40kD IgG from Camelid serum. Also according to the Examiner, the evidentiary references (particularly WO94/25591) teach that the 100 kD band in camel serum is composed of heavy chain dimers that are devoid of light chains that lack CH1 domain, and that the 40 kD material is a full camel heavy chain devoid of light chain.

Applicant respectfully disagrees with the Examiner's assertions. In fact, Ungar-Waron teaches that "Camel serum contains a complex IgG-like protein associated with an additional molecule of approximately 100,000 Daltons AMW." (See first sentence of Discussion section). Ungar-Waron then teaches that upon reduction of disulfide bonds, the complex of the IgG-like protein and the additional molecule dissociates into protein bands including one of "about 40,000 AMW." (See second sentence of Discussion section). Therefore, nowhere does Ungar-Waron teach or suggest that the 40kD protein is an IgG. In fact, none of the proteins are identified as IgG; even the protein that is associated with the 100kD protein is referred to as "IgG-like", not as an IgG.

In addition, Applicant respectfully disagrees that WO94/25591 teaches anything about the properties of the 100kD band of Ungar-Waron, such as those mentioned by the Examiner in the third bullet point on page 5 (lacking light chains, lacking CH1 domains, binding antigens). WO94/25591 does not teach that the isolated 100kD proteins are the "same as taught by Ungar-Waron" as was asserted by the Examiner. WO94/25591 merely states that the presence of considerable amounts of IgG like material of 100kD in the serum of camel was confirmed, citing the Ungar-Waron reference.

Moreover, even if the teachings of Ungar-Waron were as asserted by the Examiner, which Applicant does not concede the correctness of, the 40 kD material would thus consist of a

variable region, a hinge, a CH2 and a CH3 region (as is evidenced e.g. by the structures shown in Fig. 4 of Hamers-Casterman et al. and in Fig. 4 of WO 94/25591).

In contrast to the teachings of Ungar-Waron et al. as asserted by the Examiner, the variable region recited in the amended claims is only a small fraction of the whole heavy polypeptide chain. As is evidenced by EP 0 739 981 (see page 9, lines 43-47), the variable region of a camel heavy chain (without hinge, CH2 or CH3) has a molecular weight of only 16 kD. Nowhere in Ungar-Waron et al. is the isolation of this variable region from the full heavy polypeptide chain disclosed, taught or even suggested. Therefore, Ungar-Waron et al. does not anticipate the present claims.

Accordingly, withdrawal of the rejection under 35 U.S.C. § 102 is respectfully requested.

2. The Examiner maintained the rejection of claims 18-22, 25-27, 31-33, 35 and 51-53 under 35 U.S.C. § 102(b) as being anticipated by Grover et al. (Ind. J. Biochem. Biophys. 1983, 20(4): 238-240, as evidenced by WO 94/25591, Satija et al. (Inf. Immun. 1979, 24(2): 567-570), van der Linden et al. (Biochimica et Biophysica Acta 1999, 1431: 37-46), and EP 0739981 A1.

According to the Examiner, Grover et al. teach the IgG2 isotype polyclonal antibodies, including the reduced form (which separates the heavy chain polypeptides). Therefore, according to the Examiner, Grover et al. teach the full camel heavy chain devoid of light chain. This full camel heavy chain consist of a variable region, a hinge, a CH2 and a CH3 region (as is evidenced e.g. by the structures shown in Fig. 4 of Hamers-Casterman et al. and in Fig. 4 of WO 94/25591).

The present claims do not recite an antibody (as incorrectly stated by the Examiner). The amended claims recite a variable region of the heavy polypeptide chain of an antibody. This variable region is only a small fraction of the full heavy polypeptide chain. Nowhere in Grover et al. is the isolation of this variable region from the full heavy polypeptide chain disclosed, taught or even suggested. Therefore, Grover et al. does not anticipate the present claims.

Accordingly, withdrawal of the rejection under 35 U.S.C. § 102 is respectfully requested.

3. The Examiner rejected claims 18-22, 25-27, 31-33, 35 and 51-53 under 35 U.S.C. § 102(b) as being anticipated by Frenken et al. (J. Biotechnology, 2000, 78: 11-21).

Frenken et al. was published after the priority date of the instant application. In view of the claim amendments made herewith, Applicant submits that the present claims have the priority date of 1992. Therefore, Frenken et al. is not prior art and does not anticipate the present claims.

Accordingly, withdrawal of the rejection under 35 U.S.C. § 102 is respectfully requested.

4. The Examiner rejected claims 18-22, 25-27, 31-33, 35 and 51-53 under 35 U.S.C. § 102(b) as being anticipated by Lauwereys et al. (The EMBO Journal, 1998, 17(13): 3512-3520).

Lauwereys et al. was published after the priority date of the instant application. In view of the claim amendments made herewith, Applicant submits that the present claims have the priority date of 1992. Therefore, Lauwereys et al. is not prior art and does not anticipate the present claims.

Accordingly, withdrawal of the rejection under 35 U.S.C. § 102 is respectfully requested.

Double-Patenting Rejection

1. The Examiner provisionally rejected claims 18-22, 25-27, 31, 32 and 51-54 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-27 and 33 of co-pending Application No. 11/350,900 in view of van der Linden et al. (Biochemica et Biophysica Acta 1999, 1431: 37-46).

Applicant respectfully disagrees that claims 18-22, 25-27, 31, 32 and 51-54 are obvious over the cited claims of Application No. 11/350,900. However, to facilitate allowance of the instant claims, Applicant submits herewith a Terminal Disclaimer to obviate the rejection based on commonly owned Application No. 11/350,900.

Accordingly, withdrawal of the rejection of claims 18-22, 25-27, 31, 32 and 51-54 is respectfully requested.

2. The Examiner provisionally rejected claims 33 and 35 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-27 and 33 of co-pending Application No. 11/350,900 in view of van der Linden et al. (Biochemica et Biophysica Acta 1999, 1431: 37-46) as applied to claims 18-22, 25-27, 31, 32 and 51-54, and further in view of Harlow and Lane.

Applicant respectfully disagrees that claims 33 and 35 are obvious over the cited claims of Application No. 11/350,900. However, to facilitate allowance of the instant claims, Applicant submits herewith a Terminal Disclaimer to obviate the rejection based on commonly owned Application No. 11/350,900.

Accordingly, withdrawal of the rejection of claims 33 and 35 is respectfully requested.

CONCLUSION

A Notice of Allowance is respectfully requested. The Examiner is requested to call the undersigned at the telephone number listed below if this communication does not place the case in condition for allowance.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,
Cecile Casterman et al., Applicant(s)

By: /John R. Van Amsterdam/
John R. Van Amsterdam
Reg. No. 40,212
Wolf, Greenfield & Sacks, P.C.
600 Atlantic Avenue
Boston, Massachusetts 02210-2206
Telephone: (617) 646-8000

Docket No.: A0848.70021US08
Date: October 14, 2008
X10/14/08x